

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

RECKITT BENCKISER
PHARMACEUTICALS, INC., RB
PHARMACEUTICALS LIMITED, and
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Defendant.

Civil Action No. 5:13-CV-760

**DEFENDANT’S
MEMORANDUM IN SUPPORT OF
ITS MOTION TO STAY PENDING
INTER PARTES REVIEW**

I. NATURE AND STAGE OF THE PROCEEDINGS

Defendant BioDelivery Sciences International, Inc. (“BDSI”) respectfully submits this memorandum in support of its motion to stay this action pending *inter partes* review of the sole patent in suit.

Plaintiffs filed their Complaint for Patent Infringement (D.I. 1) on October 29, 2013, alleging that BDSI’s Bunavail™ product – a product that has neither received FDA approval nor even been marketed by BDSI – infringes U.S. Patent No. 8,475,832 (“‘832 Patent”). BDSI has moved to dismiss the Complaint for several reasons, including, *inter alia*, the fact that (i) Plaintiffs fail to state a claim for patent infringement pursuant to 35 U.S.C. § 271(e)(2), and (ii) Plaintiffs’ claim for declaratory judgment is not ripe and therefore fails to invoke this Court’s subject matter jurisdiction. The parties will complete briefing on the pending motion to dismiss on February 10, 2014 when BDSI files its reply brief.

In the event that this Court denies BDSI's motion to dismiss in whole or in part, BDSI respectfully requests that this action be stayed pending completion of the *inter partes* review proceedings that BDSI petitioned for on January 15, 2014 concerning the '832 Patent. Given (i) that this litigation is at the earliest stage, (ii) that there will be no prejudice or tactical disadvantage to Plaintiffs in the event of a stay, (iii) that the *inter partes* review proceedings will narrow, inform or resolve the issues in dispute, and (iv) the important policy considerations discussed below, BDSI respectfully submits that a stay is warranted.

II. FACTUAL BACKGROUND

BDSI respectfully refers the Court to its Memorandum in Support of its Motion to Dismiss (D.I. 19) for a recitation of the facts giving rise to this action. Below, BDSI will discuss briefly the facts relevant to the requested stay.

A. This Action Involves Only The '832 Patent

Plaintiffs market a pharmaceutical product known as Suboxone Film. Complaint ¶ 2. BDSI has developed a pharmaceutical product known as Bunavail™ for which it has sought approval through the submission of a section 505(b)(2) application to the FDA, but BDSI has not yet received that approval. Complaint ¶ 24. Until such approval is obtained, BDSI cannot market or sell Bunavail™. *See, e.g.*, Complaint ¶ 44 (“BDSI intends to engage in the commercial manufacture, use, sale or offer for sale...upon approval of its pending 505(b)(2) application”) (emphasis added). If approved, and if BDSI ultimately markets Bunavail™, it will compete with Plaintiffs' Suboxone Film product. Complaint ¶ 32. Accordingly, BDSI does not presently sell or offer for sale a competing product, but it may do so in the future. Because Plaintiffs' Complaint is premised on contingent future events (among other defects), BDSI has moved to dismiss this action (D.I. 18), which motion is currently pending.

In Count I of Plaintiffs' Complaint, they purport to seek a declaratory judgment that BDSI will infringe the '832 Patent. Complaint ¶¶ 42-49. In Count II of Plaintiffs' Complaint, they purport to assert a claim for patent infringement pursuant to 35 U.S.C. § 271(e)(2), a so-called Hatch-Waxman Act claim for patent infringement. *See id.* at ¶¶ 50-52. Importantly, both Counts concern the '832 Patent – no other patents are alleged to be infringed. Moreover, the Complaint does not contain any other counts or causes of action. Accordingly, the dispute, as framed by Plaintiffs, begins and ends with the '832 Patent.¹

B. BDSI Has Requested *Inter Partes* Review of the '832 Patent

The '832 Patent is the subject of a pending petition for *Inter Partes* Review (“IPR”) filed by BDSI on January 15, 2014 and assigned IPR No. 2014-00325. *See* Ex. 2 at 1 (IPR Petition).² The '832 Patent contains 19 claims – BDSI has initially sought *inter partes* review of claims 15-19.³ Pursuant to 35 U.S.C. §§ 314(b), 316(a)(11) and 37 C.F.R. § 42.107, the Patent and Trademark Office (“PTO”) must decide whether to institute an *inter partes* review within six months of the filing of a petition, and if instituted, must issue a final determination within 12 months of instituting the review. *See, e.g., Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at *2 n.2 (D. Del. July 2, 2013) (unpublished) (discussing timing of *inter partes* review proceedings).

¹ Though not necessarily relevant to the stay analysis, BDSI notes that the '832 Patent provides the following description of its invention: “Currently, treatment of opioid dependence is aided by administration of Suboxone® [tablet], which is an orally dissolvable tablet. This tablet which provides a combination of buprenorphine (an opioid agonist) and naloxone (an opioid antagonist). [sic] Therefore, the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides a bioequivalent effect to Suboxone® [tablets].” Ex. 3 ('832 patent) at 4:52-60.

² The true and accurate nature of exhibits 2 - 7 cited herein are attested to in the contemporaneously-filed Declaration of Richard T. Matthews In Support of Defendant's Motion to Stay Pending *Inter Partes* Review, filed as Ex. 1.

³ BDSI reserves the right to seek *inter partes* review of claims 1-14, and may do so in the future.

In light of the filing of BDSI's petition for *inter partes* review on January 15, 2014, the PTO must decide whether to institute *inter partes* review by July 30, 2014, and if instituted, the *inter partes* review must be concluded by July 30, 2015 (absent a showing of good cause that would warrant a six-month extension of the deadline for the PTO to complete its review (*see* 37 C.F.R. § 42.100)).⁴ As with traditional reexamination proceedings, *inter partes* review proceedings create additional prosecution history which may be relevant to claim construction and other issues.

Pursuant to 35 U.S.C. § 315(e), both petitioners and real parties-in-interest in *inter partes* review proceedings are bound by the PTO's final written decision. Accordingly, because BDSI is the petitioner in the request for *inter partes* review of the '832 Patent, it may be bound by estoppel in these proceedings. The estoppel provision of 35 U.S.C. 315(e) extends to "any ground that the petitioner raised or reasonably could have raised during that *inter partes* review" and may apply to this action. *See* 35 U.S.C. § 315(e)(2).

Finally, while the PTO has yet to institute *inter partes* review proceedings based on BDSI's petition, it is highly likely that the PTO will do so. The PTO institutes *inter partes* review in response to the majority of the petitions it receives. *See* Ex. 4 (Patent and Trial Appeal Board AIA Progress Statistics). Accordingly, BDSI respectfully requests that, in the event that the Court does not grant BDSI's motion to dismiss, this Court enter a stay before unnecessary judicial and party resources are expended.

C. This Litigation Is In Its Infancy

As noted above, BDSI's Motion to Dismiss (D.I. 18) is currently pending before the Court. Other than partial briefing on BDSI's Motion to Dismiss, this action has not advanced

⁴ Plaintiffs have three months from January 30, 2014 to file a preliminary response to BDSI's *IPR* petition, (*see* Ex. 5) and the PTO then has three months to decide whether to institute the requested *IPR*.

past the pleading stage. For example, the parties have not: (1) discussed scheduling; (2) exchanged Rule 26 Initial Disclosures; (3) served discovery requests; (4) exchanged drafts of a proposed protective/confidentiality order; or (5) exchanged preliminary infringement or invalidity contentions. As this lack of activity reflects, this action is truly at the very earliest stage.

III. ARGUMENT

A. Applicable Legal Standards And The Liberal Policy Favoring Stays

The determination of whether to grant a stay pending the outcome of reexamination or *inter partes* review (“IPR”) at the Patent and Trademark Office (“PTO”) is soundly within the Court's discretion. *Star Envirotech, Inc. v. Redline Detection, LLC*, SACV 12-01861 JGB, 2013 WL 1716068, at *1 (C.D. Cal. Apr. 3, 2013) (unpublished); *Cornerstone Biopharma, Inc. v. Vision Pharma, LLC*, No. 5:07-cv-00389-F, 2008 U.S. Dist. LEXIS 76374, at *3 (E.D.N.C. Feb. 15, 2008) (unpublished) (Fox, J.); *see also Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (“Courts have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a PTO reexamination”). This discretion should be exercised freely to enter a stay because this Court and others have recognized that “[t]here is a liberal policy in favor of granting motions to stay proceedings pending the outcome of PTO reexamination . . . proceedings.” *Biogaia AB v. Nature’s Way Prods., Inc.*, No. 5:10-cv-449, 2011 U.S. Dist. LEXIS 92688, at *4 (E.D.N.C. Aug. 18, 2011) (unpublished); *Cellectis S.A. v. Precision Biosciences, Inc.*, No. 5:08-CV-00119-H, 2010 WL 3430854, *3–*6 (E.D.N.C. Aug. 31, 2010) (unpublished); *see also Cima Labs, Inc. v. Actavis Group HF*, No. 07-893, 2007 U.S. Dist. LEXIS 41516, at *25-26 (D.N.J. June 7, 2007) (unpublished) (reasons underlying liberal policy include the “simplification of litigation that might result from the cancellation, clarification, or limitation of claims, and, even if the reexamination did not lead to claim

amendment or cancellation, it could still provide valuable analysis to the district court”) (internal citations omitted).

The Federal Circuit recently confirmed that the PTO’s invalidation of claims on reexamination (and implicitly, *inter partes* review) is binding on Article III courts, further underscoring the providence of granting a stay pending *IPR*. See *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1340 (Fed. Cir. 2013) (“if the PTO confirms the original claim in identical form, a suit based on that claim may continue, but if the original claim is cancelled or amended to cure invalidity, the patentee’s cause of action is extinguished and the suit fails”). *Fresenius* confirms the significant risk that the parties and the Court will be wasting their time and resources on unnecessary and duplicative proceedings if they conduct litigation in parallel with *inter partes* review. See *Zillow, Inc. v. Trulia, Inc.*, No. C12-1549JLR, 2013 WL 5530573, at *8 (W.D. Wash., Oct. 7, 2013) (unpublished) (granting stay because “this court would be relieved of having to expend substantial judicial resources in deciding claim construction, non-infringement, and invalidity issues before those claims are invalidated, narrowed, or refined through [covered business method] review”);⁵ *MonoSol Rx, LLC v. BioDelivery Sciences Intern., Inc.*, Civ. No. 10-5695, 2012 WL 762501, at *10 (D.N.J. Mar. 7, 2012) (unpublished) (“the Court finds that advancing this litigation while these reexaminations are pending may be an exercise in futility”).

Courts consider the following factors in determining whether a stay pending resolution of PTO reexamination or *inter partes* review is appropriate: (1) whether a stay will unduly prejudice or tactically disadvantage the nonmoving party; (2) whether a stay will simplify the issues and streamline trial; and (3) the stage of the litigation, including whether discovery is complete and a trial date has been set. *Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *4;

⁵ Covered Business Method (“CBM”) review is similar to *inter partes* review, but is available only with regard to patents that have at least one claim directed to a business method.

Cellectis S.A. v. Precision Biosciences, Inc., No. 5:08-CV-00119-H, 2010 U.S. Dist. LEXIS 91043, at *6; *Cornerstone Biopharma*, 2008 U.S. Dist. LEXIS 76374, at *3. Courts additionally take into account the “public policy interest in removing invalid patents from the public arena” through the reexamination process. *Rembrandt Gaming Technologies, LP v. Boyd Gaming Corp.*, No. 2:12-CV-00775-MMD, 2012 WL 6021339, at *5 (D. Nev. Dec. 3, 2012) (unpublished). As explained below, all four of these factors militate in favor of a stay pending *inter partes* review of claims 15-19 of the ‘832 Patent.

B. A Stay Will Not Unduly Prejudice Plaintiffs Or Subject Plaintiffs To A Tactical Disadvantage

A stay of this case will not present undue prejudice or a clear tactical disadvantage to Plaintiffs. While Plaintiffs may attempt to allege prejudice in a potential delay in the resolution of their case, courts have been clear that delayed resolution alone does not, by itself, amount to prejudice. *See Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *8; *Cellectis*, 2010 U.S. Dist. LEXIS 91043, at *11; *Cornerstone Biopharma*, 2008 U.S. Dist. LEXIS 76374, at *5 (delay inherent to the reexamination does not constitute, by itself, undue prejudice); *see also Stryker Trauma S.A. v. Synthes (USA)*, No. 01-3879 (JLL), 2008 U.S. Dist. LEXIS 23955, at *4 (D.N.J. Mar. 26, 2008) (unpublished) (“this Court finds that any prejudice Stryker will suffer through delay or tactical advantage, while undeniably present, does not weigh heavily in the balancing of the stay factors”).

As an initial matter, BDSI is not currently selling the accused Bunavail™ product, and assuming it is indeed approved by the FDA, there is no concrete indication as to whether or when BDSI will begin selling Bunavail™. Accordingly, Plaintiffs cannot credibly establish a real and concrete prejudice or tactical disadvantage resulting from a stay. Although Plaintiffs may argue that they will be prejudiced in the future in the event a speculative set of circumstances come to

pass, Plaintiffs will retain the right to move to lift the stay in the future upon a showing of changed circumstances tipping the scales against maintaining the stay.

Moreover, the *IPR* sought by BDSI is not the equivalent of the *inter partes* reexaminations of old, which were capable of languishing on forever. *See Semiconductor Energy Lab. Co., Ltd. v. Chimei Innolux Corp.*, No. SACV 12-21-JST JPRX, 2012 WL 7170593, at *3 (C.D. Cal. Dec. 19, 2012) (unpublished) (“the delay caused by the new *IPR* procedure is significantly less than the delay caused by the old [reexamination] procedure”). Pursuant to 35 U.S.C. §§ 314(b), 316(a)(11) and 37 C.F.R. § 42.107, the PTO must decide whether to institute an *inter partes* review within six months of the filing date afforded to a petition, and if instituted, must issue a final determination within 12 months of instituting the review. *See, e.g., Neste Oil OYJ*, 2013 WL 3353984, at *2 n.2 (discussing timing of *inter partes* review proceedings). Thus, the PTO will determine whether to institute BDSI’s requested *IPR* no later than July 30, 2014, and should conclude the *IPR* no later than July 30, 2015.⁶

The fact that the PTO has not yet granted BDSI’s *IPR* petition does not change the analysis. Statistically speaking, approximately 81% of requests for *IPR* are initiated, 9% of requests for *IPR* are denied, and settlement moots 10% *IPR* requests.⁷ *See also Evolutionary Intelligence LLC v. Yelp Inc.*, No. C-13-03587 DMR, 2013 WL 6672451, at *2 (N.D. Cal. Dec. 18, 2013) (unpublished) (noting that the PTO reviewed 88 percent of the total claims challenged in the underlying instituted petitions). In light of the PTO’s historical record of granting a majority of *IPR* petitions, Courts do not hesitate to grant a stay even in instances in which the

⁶ In rare instances, the PTO can extend by 6 months the deadline to complete an *IPR*. *See* 37 C.F.R. § 42.100. BDSI has no basis to believe the ‘832 Patent *IPR* would warrant such an extension.

⁷ *See* A Look At 1st Year Stats On Inter Partes Review, Law360.com (October 15, 2013) (available at <http://www.law360.com/articles/475994/a-look-at-1st-year-stats-on-inter-partes-review>), attached hereto as Ex. 6.

PTO has not yet instituted the requested *IPR* or reexamination. *See, e.g., Neste Oil OYJ*, 2013 WL 3353984, at *2 (acknowledging that “[t]he PTO has not yet decided to grant [petitioner’s] petition” for *inter partes* review but nonetheless granting motion to stay); *Star Envirotech, Inc.*, 2013 WL 1716068, at *2 (“As this Court has previously noted, the amended standards for granting *inter partes* review probably results in an even higher likelihood than under the prior standard that the issues in this action will be simplified by the reexamination”); *see also Air Vent, Inc. v. Owens Corning Corp.*, No. 2:10-cv-01699, 2012 U.S. Dist. LEXIS 64294, at *10 (W.D. Pa. May 8, 2012) (unpublished) (“It is not uncommon for courts to grant stays pending reexamination prior to the PTO deciding to reexamine the patents”); *Pragmatus AV, LLC v. Facebook, Inc.*, No. 11-cv-02168-EJD, 2011 U.S. Dist. LEXIS 117147, at *10 (N.D. Cal. Oct. 11, 2011) (unpublished) (rejecting plaintiff’s argument that defendant’s motion to stay was premature because it was brought prior to an initial decision on the reexamination request by the PTO); *Honeywell Int’l, Inc. v. Furuno Elec. Co.*, No. 09-3601, 2010 U.S. Dist. LEXIS 83707, at *9-10 (D. Minn. July 30, 2010) (unpublished) (granting stay prior to PTO instituting reexamination because it “will save months of potentially wasted discovery and judicial resources”).⁸ One Court summarized:

Because the litigation, although in the incipient stage, promises an abundance of venom and the attendant delay and expense in all events; because the PTO apparently will not consume much time unless the PTO perceives an important patent issue within the PTO's particular expertise; and because an important issue that appears in the litigation also appears to fall within the PTO's province and particular expertise, prudence commends resort to a stay until either the PTO declines review or, finding an important issue within the PTO's special province, the PTO grants and completes review to the benefit of the parties, the court, and the public. In other words, the investment of some time at this juncture appears wise.

⁸ Frankly, Plaintiffs would likely accuse BDSI of bringing an untimely stay motion if it waited until after the institution of the *IPR*, a near certain event.

Capriola Corp. v. LaRose Indus., LLC, 8:12-CV-2346-T-23 TBM, 2013 WL 1868344, at *3 (M.D. Fla. Mar. 11, 2013) (unpublished).

Even if BDSI's *IPR* request were to fall within the small percentage of petitions that are denied, the progression of Plaintiffs' case would be at most slightly delayed and there would no tactical disadvantage or prejudice to Plaintiffs. *See Star Envirotech, Inc.*, 2013 WL 1716068, at *2 (C.D. Cal. Apr. 3, 2013) ("if the USPTO rejects the *inter partes* requests, the stay will be relatively short"); *Capriola Corp.*, 2013 WL 1868344, at *2 ("if the PTO declines *inter partes* review, little time is lost, but if PTO grants *inter partes* review, the promise is greater for an important contribution by the PTO to resolution of the governing issues in the litigation"); *see also VDF FutureCeuticals, Inc. v. Sandwich Isles Trading Co.*, No. 11-00288, 2011 U.S. Dist. LEXIS 148766, at *4 (D. Haw. Dec. 27, 2011) (unpublished) ("the PTO should decide whether to reexamine the patents very soon. Consequently, if the PTO rejects the reexamination request, the delay caused by staying this case will be minimal").

Contrary to any claims of prejudice or tactical disadvantage that Plaintiffs' may conjure, all parties and the Court will benefit from the avoidance of duplicative efforts and proceedings, and the elimination of any risk of inconsistent results. In addition to the conservation of judicial resources, all parties will benefit from the cost savings of litigating the validity of claims 15-19 of the '832 Patent before the specialized and less costly Patent Trial and Appeals Board ("PTAB"). *Neste Oil OYJ*, 2013 WL 3353984, *at 5 (taking into account the PTO's expertise and potential for issue simplification and finding that "a stay pending review will advance the interests of judicial economy"); *Star Envirotech, Inc.*, 2013 WL 1716068, at *2 ("The Court finds that *IPR* is a procedure that aids in that enforcement of patent rights while streamlining the issues in need of litigation").

In addition to the cost savings inherent in a stay, Plaintiffs will benefit from having the PTAB determine the validity of claims 15-19 of the '832 Patent, because if those claims survive intact and unchanged following IPR, they will have been twice-blessed by the PTO, and BDSI will be estopped from making the same invalidity arguments in this case. *See* 35 U.S.C. 315(e) (providing that BDSI will be estopped from later asserting “any ground that the petitioner raised or reasonably could have raised during that inter partes review”);⁹ *see also Star Envirotech, Inc.*, 2013 WL 1716068, at *2 (finding that case would be simplified because Defendants would be barred from asserting any grounds it could have raised in *IPR*); *Semiconductor Energy Lab. Co., Ltd.*, 2012 WL 7170593, at *2 (giving “full weight” to the estoppel effect of the *IPR* proceedings); *Pegasus Dev. v. Directv, Inc.*, No. 00-1020-GMS, 2003 U.S. Dist. LEXIS 8052, at *8 (D. Del. May 14, 2003) (unpublished) (“if, after reexamination, the plaintiffs’ patents are again upheld, the plaintiffs’ rights will only be strengthened, as the challenger’s burden of proof becomes more difficult to sustain”).

Importantly, before leaving the topic of tactical disadvantage or prejudice to Plaintiffs, it bears noting that BDSI has not delayed in either seeking *IPR* of the '832 Patent claims 15-19 or moving for a stay, nor has it sought a stay for a dilatory purpose. *See Neste Oil OYJ*, 2013 WL 3353984, at *2 (finding no unreasonable delay in filing *IPR* petition and motion to stay); *Semiconductor Energy Lab. Co., Ltd.*, 2012 WL 7170593, at *2 (finding no unreasonable delay in filing *IPR*); *see also Sabert Corp. v. Waddington N. Am., Inc.*, No. 06-5423 (JAG), 2007 U.S. Dist. LEXIS 68092, at *18-19 (D.N.J. Sept. 14, 2007) (unpublished) (granting a stay when there was no evidence of dilatory tactics by defendant); *see also Methode Elecs., Inc. v. Infineon*

⁹ The estoppel provisions of 35 U.S.C. § 315 apply to final written determinations issued after the institution of an *inter partes* review (*see* 35 U.S.C. § 318(a)); if the PTO declines to institute an *inter partes* review, there will be no estoppel.

Techs. Corp., No. C 99-21142 JW2000, U.S. Dist. LEXIS 20689, at *7 (N.D. Cal. Aug 7, 2000) (unpublished) (granting a stay when defendants did not unduly delay in bringing a motion to stay). To the contrary, BDSI petitioned for *inter partes* review within 3 months of the filing of the Complaint, and is filing this Motion to Stay within 16 days of petitioning for *inter partes* review. Thus, “[t]his is not a case where reexamination is sought on the eve of trial or after protracted discovery,” such that dilatory tactics might be inferred. *KLA-Tencor Corp. v. Nanometrics, Inc.*, No. 09-3601 C 05-03116 JSW, 2006 U.S. Dist. LEXIS 15754, at *8 (N.D. Cal. Mar. 16, 2006) (unpublished); *see also Neste Oil OYJ*, 2013 WL 3353984, at *2 (“Given the prompt filing of both the petition for *inter partes* review and the motion to stay, the court cannot discern an improper dilatory motive”); *Semiconductor Energy Lab. Co., Ltd.*, 2012 WL 7170593, at *3 (finding no “prejudicial ploy” in Defendant’s filing of *IPR*).

In light of the facts that (i) Plaintiffs will not be tactically disadvantaged or prejudiced by a stay; and (ii) BDSI promptly petitioned for *inter partes* review and moved for a stay without any evidence of dilatory tactics, BDSI respectfully submits that this factor weighs heavily in favor of a stay.

C. A Stay Will Allow Time For The PTO To Narrow And/Or Resolve The Issues

Courts consistently find that stays pending PTO review simplify the issues and streamline cases for trial, particularly with respect to infringement, validity, and claim construction. *See Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *9 (finding that a stay will simplify the issues in question and streamline the trial, thereby reducing the burden of litigation on the parties and on the court); *Cellectis*, 2010 U.S. Dist. LEXIS 91043, at *15 (noting that resolution or narrowing of claim construction, infringement and validity issues through conclusion of the reexamination process would be of great value to the parties and to the Court); *Cornerstone*, 2008 U.S. Dist.

LEXIS 76374, at *6 (finding that a stay will simplify the issues and streamline the trial, thereby reducing the burden on, and preserving the resources of both the parties and the Court).

Courts have repeatedly recognized the benefits of a stay pending PTO review of the patent(s)-in-suit to be: “(1) furthering judicial economy; (2) determining validity; (3) focusing the issues, defenses, and evidence; (4) developing the prior art and prosecution history; (5) obtaining the PTO’s particular expertise; (6) encouraging settlement; and (7) reducing costs to the parties.” *Capriola Corp.*, 2013 WL 1868344, at *1; *see also Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *4-5 (quoting *Collectis*, 2010 U.S. Dist. LEXIS 91043, at *6-7).

In addition to those seven points – all of which are applicable to this case – the estoppel aspect of *inter partes* review will likely narrow BDSI’s challenges to the validity of claims 15-19, should they survive *inter partes* review. *See* 35 U.S.C. § 315(e)(2) (discussing applicability of estoppel following *inter partes* review). Courts have recognized the special nature of *inter partes* proceedings as support for granting a stay. *See, e.g., Pragmatus AV, LLC*, 2011 WL 4802958, at *3 (“When, as here, there has been no material progress in the litigation, courts in this district strongly favor granting stays pending *inter partes* reexamination”); *Ceiva Logic Inc. v. Frame Media Inc.*, No. 08-636-JVS, 2009 WL 7844245, at *4 (C.D. Cal. June 9, 2009) (unpublished).¹⁰ That BDSI may “be estopped from making the same invalidity arguments that it makes to the PTO during the [*inter partes*] review proceeding[s] (or any invalidity arguments that it could have made to the PTO)” is a significant factor weighing in favor of a stay. *See Wall Corp. v. BondDesk Grp., L.L.C.*, CA 07-844 GMS, 2009 WL 528564, at *1 (D. Del. Feb. 24, 2009) (unpublished); *see also Ceiva Logic*, 2009 WL 7844245, at *4. While this may not

¹⁰ The same rationale for granting a stay pending completion of *inter partes* reexamination – *i.e.* that the PTO proceedings will simplify issues to be addressed in a litigation proceeding – applies with equal force to a stay pending *inter partes* review.

eliminate all grounds of invalidity for any surviving claims, it will certainly go a long way toward focusing the issues for trial. *See Polaris Indus., Inc. v. BRP US Inc.*, No. 12-01405, 2012 WL 5331227, at *3 (D. Minn. Oct. 29, 2012) (unpublished) (“If BRP later attempts to offer prior art it should have had previous access to, Polaris may assert estoppel and seek to preclude any related invalidity claims”); 35 U.S.C. § 315(e).

Moreover, the PTAB’s views on claim construction will inform, if not simplify, the claim construction exercise and infringement analysis in this case. *See, e.g., e-Watch, Inc. v. Lorex Canada, Inc.*, C.A. No. H-12-3314, 2013 WL 5425298, at *2 (W.D. Tex. Aug. 9, 2013) (unpublished) (expressing “legitimate concern” that parties will “participate in a claim construction hearing for patent claims that may be limited, changed or invalidated by the USPTO” and noting that the PTO’s expertise will assist the Court) (citation omitted); *St. Clair Intellectual Property Consultants, Inc. v. Canon Inc.*, 412 Fed. Appx. 270, 276 (Fed. Cir. 2011) (unpublished) (“Because an examiner in reexamination can be considered one of ordinary skill in the art, his construction of the asserted claims carries significant weight”); *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, No. 4:03-cv-40493 2004, U.S. Dist. LEXIS 16812, at *13 n.8 (S.D. Iowa Aug. 24, 2004) (unpublished) (“[T]he scope of the patent claims, which the PTO may narrow or otherwise limit, controls the outcome of any subsequent infringement analysis”).

In particular, awaiting the outcome of reexamination is beneficial to claim construction and infringement analysis because it further develops the intrinsic evidence record with the expertise at the PTO. *Semiconductor Energy Lab. Co., Ltd.*, 2012 WL 7170593, at *2 (noting that *IPR* will “facilitate trial by providing the court with expert opinion of the PTO and [clarify] the scope of the claims”); *AT&T Intellectual Property I v. TiVo Inc.*, 774 F. Supp. 2d 1049, 1053 (N.D. Cal. 2011) (“the court may have a richer prosecution history upon which to base necessary

claim construction determinations”); *Collectis*, 2010 U.S. Dist. LEXIS 91043, at *15; *Alza Corp. v. Wyeth & Wyeth Pharms., Inc.*, No. 9:06-CV-156, 2006 U.S. Dist. LEXIS 94962, at *6 (E.D. Tex. Nov. 21, 2006) (unpublished) (“Because statements made during the reexamination proceedings become part of the prosecution history, a stay will allow the intrinsic evidence to be fully developed before [the] court begins the claim construction process”). Thus, statements and evidence presented during the *inter partes* review will become additional and important intrinsic evidence that will impact the claim construction and infringement analyses.

As one Court recently observed, “the stricter standard for instituting such [*inter partes*] review suggests a greater likelihood that the PTO will cancel at least some of the challenged claims.” *Neste Oil OYJ*, 2013 WL 3353984, at *4 (citing *Universal Elecs., Inc. v. Universal Remote Control, Inc.*, No. 12–329–AG, 2013 WL 1876459, at *4 (C.D. Cal. May 2, 2013)). As such, should the petitions for *inter partes* review be granted, there is a high probability that one or more of claims 15-19 may not have to be addressed by the Court. Should the PTO then determine that claims 15-19 are invalid, the case is over as to those claims. See *Fresenius USA*, 721 F.3d at 1340; *Broadcast Innovation, L.L.C. et al. v. Charter Commc’n, Inc.*, 943 F.Supp 2d 1028, 1030 (D. Colo. July 11, 2006) (unpublished) (“[A] decision by the Patent Office that the reexamined claims of an issued patent are cancelled as unpatentable renders the claims unenforceable in the pending litigation and in any future disputes”).

The fact that some claims not challenged by BDSI at the PTO may eventually need to be addressed by the Court is not reason to prevent the stay with respect to the other claims in suit. *e-Watch, Inc.*, 2013 WL 6334372, at *7-9 (noting that even though only three of four patents were submitted for *IPR*, a stay will streamline issues, lower costs, and conserve resources); *Robert Bosch Healthcare Sys., Inc. v. ExpressMD Solutions, LLC*, No. C 12-00068, 2013 WL

752474, at *4 (N.D. Cal. Feb. 27, 2013) (unpublished) (granting stay despite no PTO challenge of some patents because “there is no requirement that reexamination resolve all issues in a case in order to warrant a stay”); *Protectconnect, Inc. v. Leviton Mfg. Co.*, No. 10cv758, 2011 U.S. Dist. LEXIS 44045, at *10 (S.D. Cal. Apr. 22, 2011) (unpublished) (granting motion to stay infringement action involving six patents even though reexamination of only two of the patents-in-suit was pending). A stay is warranted if it will simplify the issues in question; elimination of all issues is not required. *See Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *9.¹¹

In sum, courts considering a motion to stay a patent infringement action pending the outcome of PTO review of the patent(s)-in-suit have recognized that reexamination or *inter partes* review will likely narrow the issues presented and potentially avoid unnecessary litigation. Indeed, this is the very purpose behind the availability of review procedures at the PTO. *See, e.g., e-Watch, Inc.*, 2013 WL 6334372, at *9 (“continuing to prosecute this case is likely to result in the unnecessary expenditure of the parties' and the Court's resources on claims and issues that could be resolved or changed as a result of the *IPR* proceedings”); *Capriola Corp.*, 2013 WL 1868344, at *3; *see also Canady v. Erbe Elektromedizin GmbH*, 271 F. Supp. 2d 64, 68 (D.D.C. July 31, 2002) (“The purpose of the [reexamination procedure] is to allow the reexamination of patent validity in an impartial forum at almost 100 times less cost to the parties by people trained to understand the technologies described in patents”) (citations omitted). “Instead of expending significant resources on litigation and discovery at this time, particularly with regard to claims and issues that very likely will be affected by the decision of the PTO, a

¹¹ Plaintiffs have not yet identified which claims they intend to assert against BDSI. To the extent Plaintiffs contend that the analysis of whether to stay this case turns on the claims that they will assert, they should specifically identify which claims they will be asserting, and likewise, covenant not to assert the remaining claims.

stay offers the potential of simplifying the issues and giving both parties a more accurate idea of how to best direct their energies.” *Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *7-8.

Accordingly, BDSI respectfully submits that in light of the near certainty that the ‘832 Patent *IPR* will, at a minimum, simplify and narrow the issues in dispute, this factor weighs heavily in favor of a stay.

D. The Early Stage of Litigation Favors a Stay

“Here, the early stage of this litigation weighs heavily in favor of granting a stay pending reexamination.” *Cornerstone*, 2008 U.S. Dist. LEXIS 76374 at *4; *see also Biogaia AB*, 2011 U.S. Dist. LEXIS 92688, at *6 (“[t]he fact that discovery has just begun makes a stay particularly attractive, as the parties can conserve resources while awaiting the determination of the PTO, resources that otherwise would be spent on what is likely to be a lengthy and costly discovery”); *ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994) (granting a stay where parties had undertaken little or no discovery and the case had not yet been set for trial); *see also Star Envirotech, Inc.*, 2013 WL 1716068, at *2 (“the fact that this litigation is a very an (sic) early stage weighs in favor of granting the stay” pending *IPR*). In the instant case, the parties have not even completed briefing on BDSI’s Motion to Dismiss, and discovery has not begun. These facts confirm that this case is still in the early stages and that the parties have not yet invested any substantial expense. Indeed, much work remains in this case, including: (1) completing all fact and expert discovery; (2) engaging in claim construction briefing; (3) conducting a claim construction hearing; (4) filing any dispositive motions; (5) scheduling a trial date; and (6) engaging in trial preparations. The Court has yet to conduct a case scheduling conference or to set a schedule. Cutting off further, and potentially futile, expenditure of time and resources by both the parties and the Court thus weighs in favor of granting a stay at this stage of the litigation. *See*

Cellectis, 2010 U.S. Dist. LEXIS 91043, at *8; *see also Wall Corp.*, 2009 WL 528564, at *2 (the defendant’s filing of a motion to stay “early in the case, prior to the court’s scheduling conference and entry of a scheduling order . . . weighs in favor of granting a stay”).

Accordingly, Plaintiff respectfully submits that in light of the fact that this case is indisputably at the earliest possible stage, this factor weighs heavily in favor of a stay.

E. Public And Patent Policy Favor Granting A Stay

The law abhors invalid patents. *See, e.g., Application of Thorington*, 418 F.2d 528, 537 (C.C.P.A. 1969) (affirming double patenting refusal because “public policy . . . abhors improper extensions of monopoly”). Indeed, invalid patents undermine the fundamental bargain of patent law, in that they provide no public benefit in exchange for the competition-harming and public-harming monopoly they establish. *See Nestier Corp. v. Menasha Corp.-Lewisystems Div.*, 739 F.2d 1576, 1581 (Fed. Cir. 1984) (“stronger public interest in the elimination of invalid patents . . .”); *Ditto, Inc. v. Minnesota Min. & Mfg. Co.*, 336 F.2d 67, 69 (8th Cir. 1964) (“It is recognized that the public has a substantial interest in all patent litigation and is entitled to protection against monopolization of that which is not lawfully patentable”); *Pope Mfg. Co. v. Gormully*, 144 U.S. 234 (1892) (holding that it is “important to the public that competition should not be repressed by worthless patents”). As such, the PTO review proceedings are statutory rights created to give aggrieved parties, such as BDSI, the ability to remove bad patents and their undeserved monopolies from the books. *See In re Recreative Techs. Corp.*, 83 F.3d 1394, 1396–97 (Fed. Cir. 1996) (“The reexamination statute’s purpose is to correct errors made by the government . . . and if need be to remove patents that never should have been granted”).

Indeed, many Courts have granted stays to prevent the injustice ensuing from the enforcement of an invalid patent, finding proceedings in the PTO to be a sound basis to

postpone judgment until the PTO proceedings have run their course. *See Smith & Nephew, Inc. v. Interlace Med., Inc.*, Civ. No. 10-10951-RWZ, 2013 WL 3289085, at *9 (D. Mass. June 27, 2013) (unpublished) (staying permanent injunction until the conclusion of co-pending reexaminations because “the harm to defendants if the injunction were to issue on invalid patents is much greater than the harm to plaintiffs should the injunction not issue at all”); *Bausch & Lomb Inc. v. Alcon Labs, Inc.*, 914 F. Supp. 951, 925–53 (W.D.N.Y. 1996) (granting stay to avoid potential for irreparable harm if accused infringer is ordered to pay damages on a patent later determined invalid). Thus public policy underlying patent law supports granting the stay in this case.

Moreover, a stay is the only way to prevent inefficiencies created by inconsistent rulings. While a prior holding of validity by a court is not dispositive of ongoing or subsequent patent office proceedings, *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008), the PTO’s invalidation of claims during review is binding on Article III courts. *Fresenius*, 721 F.3d at 1340. Thus, if the case is not stayed and the Court determines that claims 15-19 of ‘832 Patent are not invalid, the PTO must nonetheless proceed to determine the validity of those claims for itself. *Swanson* at 1377-78. This could well lead to the inconsistent result of the Court finding validity and infringement of a patent that is later invalidated by the PTO. *eSoft, Inc. v. Blue Coat Sys., Inc.*, 505 F. Supp. 2d 784, 788 (D. Colo. 2007) (a stay will preclude inefficiencies created by potential inconsistencies between determinations by the court and the PTO). In that event, the Court and the parties will have wasted time and resources incurred in the litigation and enforcement of claims that were invalid all along. *See Softview Computer Prods. Corp. v. Haworth, Inc.*, No. 97-8815, 2000 U.S. Dist. LEXIS 11274, at *8-9 (S.D.N.Y. Aug. 10, 2000). Only a stay will mitigate this significant concern.

Accordingly, BDSI respectfully submits the foregoing policy concerns weigh heavily in favor of a stay.

IV. CONCLUSION

In the event that this litigation is not dismissed for the reasons set forth in BDSI's Motion to Dismiss (D.I. 18), BDSI respectfully requests that the Court stay this litigation pending completion of the '832 Patent *IPR* requested by BDSI on January 15, 2014. As reflected above, all of the factors relevant to the stay analysis weigh heavily in favor of a stay, as do important policy considerations. For these reasons, BDSI respectfully submits that this is not a close call – this is a case that should be stayed pending completion of the '832 Patent *IPR*.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing DEFENDANT'S MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY PENDING *INTER PARTES* REVIEW was filed, this January 31, 2014, via ECF which will send electronic notification to the following counsel of record for Plaintiffs:

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